

REMARKS

In the Office Action, the Examiner rejected claims 1-40. By this Response, Applicants have amended claims 1 and 7, and canceled claim 6. Upon entry of the amendments, claims 1-5 and 7-40 will remain pending in the present application. In view of the following remarks, Applicants respectfully request reconsideration and allowance of the pending claims.

Rejections Under § 102

In the Office Action, the Examiner rejected claims 1-4 under 35 U.S.C. § 102(b) as anticipated by Kieffer, III et al. (U.S. Patent No. 4,380,998; hereinafter “Kieffer”). Specifically, in regard to independent claim 1, the Examiner stated:

In regards to claim 1, Kieffer, III et al. disclose a cover for use with an endoscope, comprising: a body 41 having a recesses portion configured to releasably secure to an insertion portion of the endoscope (see Fig. 2).

Office Action mailed June 26, 2005, p. 2 (emphasis in original).

In light of the foregoing amendment to claim 1, which in its present form recites subject matter of cancelled claim 6, Applicants traverse the rejection of claim 1 under Section 103, as stated below. That is, because claim 6 was rejected under 35 U.S.C. § 103, the patentability of amended claim 1 is discussed below.

Rejections Under § 103

In the Office Action, the Examiner rejected claims 5-40 as obvious in view of various combinations and permutations of Kieffer, a first Yabe et al. reference (U.S. Patent No. 5,458,133; hereinafter “Yabe ‘133”), a second Yabe et al. reference (U.S. Patent No. 5,514,074; hereinafter “Yabe ‘074”), and Moriyama (U.S. Patent App. Pub. No. 2002/0013510; hereinafter “Moriyama”). Applicants address each of these rejections in turn below.

Legal Precedent

In summary, Applicants submit that the foregoing Section 103 rejections are not *prima facie* sufficient. The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). To establish a *prima facie* case, the Examiner must show two things. *See Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985). The Examiner must first show that the combination or modification includes *all* of the claimed elements. *See id.* Additionally, the Examiner must present a convincing line of reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *See id.* Moreover, obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination or modification. *See ACS Hospital Systems, Inc. v. Montefiore Hospital*, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Indeed, the mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *See In re Mills*, 16 U.S.P.Q.2d. 1430 (Fed. Cir. 1990).

With particular relevance to the present situation, and as is discussed further below, non-analogous art cannot properly be pertinent prior art under 35 U.S.C. § 103. *In re Pagliaro*, 210 U.S.P.Q. 888, 892 (C.C.P.A. 1981). For the teachings of a reference to be prior art under 35 U.S.C. § 103, there must be some basis for concluding that the reference would have been considered by one skilled in the particular art working on the particular problem with which the invention pertains. *In re Horne*, 203 U.S.P.Q. 969, 971 (C.C.P.A. 1979). The determination of whether a reference is from a non-analogous art is set forth in a two-step test given in *Union Carbide Corp. v. American Can Co.*, 724 F.2d 1567, 220 U.S.P.Q. 584 (Fed. Cir. 1984). In *Union Carbide*, the court found that the first determination was whether “the reference is within the field of the inventor’s endeavor.” If it is not, one must proceed to the second step “to determine whether the reference is

reasonably pertinent to the particular problem with which the inventor was involved.” In regard to the second step, *Bott v. Fourstar Corp.*, 218 U.S.P.Q. 358 (E.D. Mich. 1983) determined that “analogous art is that field of art which a person of ordinary skill in the art would have been apt to refer in attempting to solve the problem solved by a proposed invention.” “To be relevant the area of art should be where one of ordinary skill in the art would be aware that similar problems exist.” *Id.*

Furthermore, the Federal Circuit has consistently held that a reference that teaches away from the claimed invention cannot serve to create a *prima facie* case of obviousness. *See In re Gurley*, 31 U.S.P.Q. 2d 1130, 1132 (Fed. Cir. 1994) (noting that it is a useful general rule that “a reference that ‘teaches away’ cannot serve to create a *prima facie* case of obviousness”). Along this vein, an obviousness analysis requires that a reference must be considered in its entirety, including portions that would *lead away* from the claimed invention. *See M.P.E.P. § 2142.02* (8th ed.; Rev. 02). Indeed, “[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it that will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.” *In re Wesslau*, 147 U.S.P.Q. 391, 393 (C.C.P.A. 1965).

Additionally, in presenting a Section 103 rejection, the Examiner must provide *objective evidence*, rather than subjective belief and unknown authority, of the requisite motivation or suggestion to combine or modify the cited references. *See In re Lee*, 61 U.S.P.Q.2d. 1430 (Fed. Cir. 2002). “Broad conclusory statements standing alone are not ‘evidence’.” *In re Kotzab*, 55 U.S.P.Q. 2d 1314, 1317 (Fed. Cir. 2000). Thus, when prior art references require a selected combination or modification to render obvious a subsequent invention, there must be some reason for the combination or modification *other than the hindsight* gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the

combination or modification. *See Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988). Indeed, the Federal Circuit has warned that the Examiner must not “fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.” *See In re Dembiczak* 50 U.S.P.Q. 2d 52 (Fed. Cir. 1999). (quoting *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983)). Moreover, avoiding hindsight reconstruction is especially important regarding less technologically complex inventions, where the very ease which the invention can be understood may prompt one to employ such hindsight. *See id.*

As discussed above, in determining the differences between the prior art and the claims, the question under Section 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *See Stratoflex, Inc. v. Aeroquip Corp.*, 218 U.S.P.Q. 871 (Fed. Cir. 1983). Thus, the Examiner must not look at each element of a claim individually, but rather the claims should be viewed as a tapestry comprising the recited elements. Thus, “it is impermissible, however, to simply engage in a hindsight reconstruction of the claimed invention, *using the applicant’s structure as a template* and selecting elements from references to fill the gaps.” *In re Gorman*, 18 U.S.P.Q. 2d 1885, 1888 (Fed. Cir. 1991) (emphasis added). Simply put, what may seem logical to combine in retrospect and after viewing an applicant’s invention is not obvious unless the cited references, without benefit of this hindsight, teach what is claimed. *See In re Zurko*, 42 U.S.P.Q.2d 1476, 1479 (stating “[w]hile in retrospect, looking at applicants’ invention, it might seem logical to perform a repeat-back in the UNIX system over a trusted line, neither UNIX nor FILER2 teaches communications with the user of a trusted pathway,” as is recited in the claim in question). In summary, a valid Section 103 rejection must articulate and support with objective evidence a line of reasoning that establishes why one of ordinary skill in

the art, with no knowledge of an applicant's intention, would make the combination in the manner claimed. *See In re Kotzab*, 55 U.S.P.Q. at 1318 (Fed. Cir. 2000).

With the foregoing legal precedent in mind, Applicants respectfully assert that the pending claims are not obvious in view of the cited references, whether taken alone or together.

Kieffer Is Non-Analogous Art as Applied to Claims To An Endoscope Cover.

The Examiner is reminded that non-analogous art cannot properly be pertinent prior art under 35 U.S.C. § 103. *In re Pagliaro*, 210 U.S.P.Q. 888, 892 (C.C.P.A. 1981). For the teachings of a reference to be prior art under 35 U.S.C. § 103, there must be some basis for concluding that the reference would have been considered by one skilled in the particular art working on the particular problem with which the invention pertains. *In re Horne*, 203 U.S.P.Q. 969, 971 (C.C.P.A. 1979). The determination of whether a reference is from a non-analogous art is set forth in a two-step test given in *Union Carbide Corp. v. American Can Co.*, 724 F.2d 1567, 220 U.S.P.Q. 584 (Fed. Cir. 1984). In *Union Carbide*, the court found that the first determination was whether "the reference is within the field of the inventor's endeavor." If it is not, one must proceed to the second step "to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved." In regard to the second step, *Bott v. Fourstar Corp.*, 218 U.S.P.Q. 358 (E.D. Mich. 1983) determined that "analogous art is that field of art which a person of ordinary skill in the art would have been apt to refer in attempting to solve the problem solved by a proposed invention." "To be relevant the area of art should be where one of ordinary skill in the art would be aware that similar problems exist." Id.

In applying the first step of the above test to the present case, Applicants submit that the prior art used in this case is not within the field of the inventors' endeavor.

Specifically, Kieffer teaches a device apparently meant to aid clinicians specializing in medicine related to an anatomical part, such as an ear, a nose and/or a throat. In contrast, the Applicants' endeavor is in a field of medicine related to internal anatomical cavities, some of which may include internal organs and tissues. This is the clear field of use of an endoscope. The mere fact that the device claimed in the present patent application and the one disclosed in Kieffer are both used in the general field of medicine is insufficient to regard them as in the same field. Applicants submit that a speculum used as a part of an otoscope to probe an ear canal clearly is not an instrument that would be used in the field of internal medicine. Clearly, an endoscope is uniquely designed to probe parts of the body where otoscopes simply cannot, and visa versa.

This point is an important one insomuch as the invention concerns a cover for an endoscope. No such cover could or would be used when the endoscope itself is in use (i.e., within a body cavity of a patient). Exactly conversely, Kieffer's otoscope cover would *only* be used during examinations as it is intended to facilitate use of the otoscope *and* to promote patient comfort. Therefore, the Keiffer device is clearly not in the field of the inventors' endeavor.

In applying the second step in the above test, Applicants submit that Kieffer is not reasonably pertinent to the particular problem with which the inventors are involved. Here again, the device taught by Kieffer is aimed at providing safety and comfort *for the patient* during a medical examination of the ear. *See*, Kieffer, col. 1, lines 55-56. Accordingly, the speculum taught by the cited reference is meant to protect the ear canal as it is probed. The endoscope cover presently claimed is meant to protect *an endoscope* while it is *not in use*. Indeed, the claimed endoscope cover would never be used while the endoscope is in use. These are two very distinct problems. As one having ordinary skill in the art would appreciate, a design of a cover for an apparatus used in a medical procedure, whereby the cover may contact delicate organs of a human body during a

procedure (as in Kieffer), is clearly distinct from a design of a cover configured to protect an apparatus, such as an endoscope, while not in use. Accordingly, Kieffer is not reasonably pertinent to the particular problem with which the inventors are involved. Accordingly, Applicants submit that subject matter taught by the Kieffer reference is non-analogous art.

Amended Claim 1 Is Patentable Inasmuch As Disinfecting Compound Would Not Be Used With An Endoscope During A Medical Examination.

In the Office Action, the Examiner rejected dependent claim 6 under Section 103(a) as obvious in view of Kieffer and Yabe '074. Applicants have included subject matter recited in claim 6 into independent claim 1. Because the subject matter of claim 6 cannot be anticipated by Kieffer, Applicants traverse the rejection of claim 1 under Section 103.

First, Applicants reiterate that Kieffer cannot support a *prima facie* case of obviousness of claim 1 as it is non-analogous art.

Moreover, in its amended form independent claim 1 recites “[a] *cover* for use with an *endoscope*, comprising: a body having a recessed portion configured to releasably secure to an insertion portion of the *endoscope* and; a *disinfecting compound* disposed thereon.” (Emphasis added). In contrast, Kieffer discloses a device specifically designed to be used with an otoscope. Specifically, Kieffer teaches a removable speculum which contains a “rubber-like tip bounded upon the distal end thereof for *protecting the ear canal* and forming a seal therewith.” *See*, Kieffer, Abstract and Fig. 1. Hence, the speculum 40 taught by Kieffer is meant to be used with an otoscope in order to protect the ear canal during a medical examination.

Applicants' claimed endoscope cover is clearly *not* meant to be used during any medical procedure. In fact, as may be appreciated by one of ordinary skill in the art, using the claimed endoscope cover during a medical procedure would render the endoscope inoperable, not to mention hazardous. An endoscope is a medical device inserted into internal body cavities to inspect and perform medical procedures therein. It would be inconceivable for a clinician to use an endoscope with a cover, especially a cover having a potential of disengaging from the endoscope while it is disposed in a human cavity during the procedure.

That is, the only logical combination of the references would provide a cover (which would necessarily be readapted from a speculum and made for an endoscope) used with the endoscope, with an integrated disinfecting compound. While it may be practical and safe to insert the speculum of Kieffer into an ear canal while the speculum has a disinfecting compound (this, too, might be questionable), it is categorically impractical, much less unsafe to insert an endoscope into an internal body cavity with a cover having a disinfected compound disposed thereon. Hence, any attempt to obviate the claimed endoscope cover by combining Kieffer and Yabe '074 would fail because the device achieved by their combination would yield an endoscope operable in a human body with a cover having a disinfected material disposed thereon.

Consequently, the combination of Kieffer and Yabe '074 clearly does not and cannot establish a *prima facie* case of obviousness of claim 1 or its dependent claims.

The Tape Indicators Of Yabe '133 Would Never Be Used With An Invasive Instrument Such As An Endoscope.

The Examiner rejected all of the remaining independent claims 8, 15, 22, 27, 30 and 36 over a combination of Kieffer with Yabe '133.

Applicants here again reiterate that Kieffer cannot support a *prima facie* case as it is non-analogous art.

Moreover, the rejection of independent claims 8, 15, 22, 27, 31 and 36 is improper because the combination is unworkable. For example, independent claim 8 recites a body of a cover of an endoscope “wherein the body includes an *indicium* configured to indicate a condition of the endoscope.” (Emphasis added). Independent claim 15 recites “the first cover member comprises a first *indicium* indicative of a first endoscope condition.” Similarly, independent claims 22, 27, 31 and 36 also recite endoscope covers having an indicium to indicate the state or condition of the endoscope.

In contrast, Yabe ‘133 discloses tape that can be directly applied to a device to indicate where cleaning is required (“for example, a blue colored tape 30B for indicating a clean area”). *See*, Yabe ‘133, col. 4, lines 36, 37; and Fig. 2. Accordingly, Yabe ‘133 teaches an indicium in the form of a tape indicating areas of an endoscope to be cleaned. The combination of Yabe ‘133 and Kieffer would yield an otoscope with a cover or speculum, apparently to which tape would be applied to indicate where cleaning is needed. Apparently the Examiner would have the speculum, then, reconfigured as an endoscope cover. However, Kieffer’s speculum, used only when the otoscope is used does not teach a cover that would, conversely, be used only when an endoscope is *not* in use, Applicants can reach no other conclusion. The tapes of Yabe ‘133 would never, of course, be used during use of an endoscope.

Further, even if *arguendo* the art could be combined, Applicants see no motivation whatsoever for adding the tape of Yabe ‘133 to an endoscope cover. The entire purpose of the Yabe ‘133 tape is to indicate specific locations on an endoscope to be cleaned. Somehow applying tape to the claimed cover would clearly defeat this purpose and would indicate no particular locations at all.

Because of these deficiencies a *prima facie* case of obviousness cannot be established with regard to claims 8, 15, 22, 27, 31 and 36. Accordingly, Applicants request the Examiner to remove the rejections and allow independent claims 8, 15, 22, 27, 31 and 36 and dependent claims therefrom.

Claims 19-21 and 37-40 are Allowable

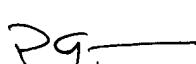
In the Office Action, dependent claims 19-21 and 37-40 were rejected under Section 103 as obvious in view of various reference combinations. Applicants, however, respectfully submit that these claims, which depend from the independent claims discussed above, are patentable by virtue of their respective dependencies on allowable based claims, and also by virtue of the additional features recited therein. Therefore, Applicants respectfully request reconsideration and allowance of these claims.

Conclusion

Applicants respectfully submit that all pending claims should be in condition for allowance. However, if the Examiner believes certain amendments are necessary to clarify the present claims or if the Examiner wishes to resolve any other issues by way of a telephone conference, the Examiner is kindly invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

Date: March 9, 2006



Patrick S. Yoder
Registration No. 37,479
FLETCHER YODER
P.O. Box 692289
Houston, TX 77269-2289
(281) 970-4545